

## **REMARKS/ARGUMENTS**

Reconsideration of the present application, as amended, is respectfully requested.

Since the present amendment raises no new issues for consideration and, in any event, places the present application in better condition for consideration on appeal, it is respectfully requested that this amendment be entered under 37 CFR 1.116 in response to the last Office Action dated February 7, 2007, which made final rejections as to the pending claims.

### **A. STATUS OF THE CLAIMS**

As a result of the present amendment, claims 1, 3-5 and 7-8 are presented in the case for continued prosecution. Claim 1 as amended herein includes 20-80 weight % of a mixture which contains 98-99 weight % of calcium sulfate, 0.3-1 weight % of  $\text{CaCO}_3$ , 0.3-1 weight % of  $\text{MgCO}_3$  and 0.5-1 weight % of  $\text{CaCO}_3 \cdot \text{MgCO}_3$ . Support can be found, for example, at page 14, line 25 through page 15, line 4; Table 1 at page 23; and original claim 2. Claim 2 has been cancelled without prejudice. Claim 8 has been amended to recite the ratio of calcium sulfate to carboxymethylcellulose. Support can be found, for example, at Example 1 at page 22 of the specification and in original claims 4-5. No new matter has been added.

### **B. SUMMARY OF THE INVENTION**

The gel-type bone-filling compositions as amended herein include (a) 20-80 weight % of a mixture containing 98-99 weight % of calcium sulfate, 0.3-1 weight % of  $\text{CaCO}_3$ , 0.3-1 weight % of  $\text{MgCO}_3$  and 0.5-1 weight % of  $\text{CaCO}_3 \cdot \text{MgCO}_3$  and (b) 80-20 weight % of a viscous biopolymer. The gel-type compositions are prepared by mixing the mixture of calcium sulfate,  $\text{CaCO}_3$ ,  $\text{MgCO}_3$  and  $\text{CaCO}_3 \cdot \text{MgCO}_3$  with the viscous polymer. See page 15, lines 14-16; and Example 1 at page 22 of the specification. The gel-type compositions of the present invention remain where administered, and help stimulate bone-formation and bone-consolidation via efficient mineralization.

### **C. THE CLAIMS ARE NOT RENDERED OBVIOUS BY PETERSEN IN VIEW OF LIU**

At pages 3-6 of the Office Action, the Examiner has rejected the subject matter of pending claims under 35 U.S.C. 103(a) as allegedly unpatentable over Petersen et al. (US Patent

Publication No. 2002/0071827) in view of Liu et al. (US Patent No. 5,281,265). The Examiner has alleged that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add one or more inorganic salts selected from the group consisting of  $\text{CaCO}_3$ ,  $\text{MgCO}_3$ ,  $\text{CaCO}_3\cdot\text{MgCO}_3$ , as suggested by Liu et al. to the composition of Petersen et al. and produce the present invention.

In *KSR Int'l v. Teleflex, Inc.*, 550 U.S. \_\_\_\_ (2007), the Supreme Court rejected the CAFC's "teaching, suggestion, or motivation" test (TSM test) for obviousness. The Court appears to affirm the broader conception of the TSM test in *DyStar Textilfaben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (2006). The broad test provides that common knowledge and common sense can be considered, or a motivation to combine prior art references can be found implicitly. Considering the decision in the KSR court, and the flexible test mentioned in the opinion, it is urged that the Examiner has still not met the legal burden of sustaining a *prima facie* case of obviousness.

It is also urged that *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1996) remains good law. Even with the holding of *KSR Int'l v. Teleflex, Inc.*, Id., the Patent Office must still meet its burden of asserting a *prima facie* case of obviousness before turning to the inquiries set forth in *Graham Id.*, for claim analysis under 35 U.S.C. 103. Thus, it is submitted that the Examiner cannot shift the burden of proof to the Applicants' until providing a *prima facie* allegation of obviousness. Absent such a showing, it is urged that the Applicant need not come forward with one or more of the Graham factors, such as a showing of unexpected results.

Petersen et al. describes bone graft substitute compositions consisting essentially of (a) calcium sulfate, (b) a mixing solution such as water and inorganic salts, and (c) a plasticizing substance such as carboxymethylcellulose. Compositions of Petersen include three components, for example, (a) 80-120 parts by weight calcium sulfate, (b) 21-250 parts by weight water, and (c) 1-40 parts by weight plasticizing agent. See paragraph [0019] of the reference.

Liu et al. describes to surgical cements which harden into biocompatible hardened cements. The cements of Liu et al. include (a) a cementing component such as calcium sulfate; (b) a setting component; (c) a biocompatible filler component; and (d) water. The Examiner states that Liu et al. teaches "a biocompatible filler component selected from the group

consisting of calcium carbonate, magnesium carbonate and mixtures thereof (Claims 1, 15 and 16)". See page 4, last paragraph of the Office Action.

Applicants respectfully draw the Examiner's attention to the fact that Liu et al., at most, discloses calcium carbonate as pertinent to the claimed invention.  $\text{MgCO}_3$  and  $\text{CaCO}_3\cdot\text{MgCO}_3$  are not described by Liu. Please see column 4, lines 41-53 and claim 16 of the reference. Liu et al. does not teach or suggest explicitly or implicitly modifying the compositions of Petersen to include a mixture containing 98-99 weight % of calcium sulfate, 0.3-1 weight % of  $\text{CaCO}_3$ , 0.3-1 weight % of  $\text{MgCO}_3$  and 0.5-1 weight % of  $\text{CaCO}_3\cdot\text{MgCO}_3$ . In fact, Liu teaches "The weight ratio of the fillers to the cementing components can be up to 4 to 1." See column 4, lines 52-53. Thus, according to the teaching of the Liu et al. reference, the weight ratio of calcium carbonate to calcium sulfate can be up to 4 to 1. On the other hand, the claimed invention includes calcium sulfate:  $\text{CaCO}_3$ :  $\text{MgCO}_3$ :  $\text{CaCO}_3\cdot\text{MgCO}_3$  in a weight % ratio of 98-99: 0.3-1: 0.3-1: 0.5-1.

Thus, it is urged that even if those skilled in the art modified the composition of Petersen et al. as hypothesized by the Examiner in view of Liu et al., the alleged compositions would still not contain calcium sulfate,  $\text{CaCO}_3$ ,  $\text{MgCO}_3$  and  $\text{CaCO}_3\cdot\text{MgCO}_3$  in an amount of 98-99 weight %, 0.3-1 weight %, 0.3-1 weight % and 0.5-1 weight % of the mixture, respectively. Additionally, unlike the Examiner's alleged compositions, the claimed invention does not include the 21-250 parts by weight of a mixing solution such as water as stated by Petersen. The calcium sulfate,  $\text{CaCO}_3$ ,  $\text{MgCO}_3$  and  $\text{CaCO}_3\cdot\text{MgCO}_3$  are mixed with the viscous biopolymer in the Applicants' claimed gel-type compositions. As such, the claimed invention is submitted to be fully distinguishable from the compositions of Petersen et al., even in view of Liu, et al.

Contrary to the Examiner's position that "determining an appropriate amount of  $\text{CaCO}_3$ :  $\text{MgCO}_3$ :  $\text{CaCO}_3\cdot\text{MgCO}_3$  to add to the composition is deemed merely a matter of routine optimization", (see page 6, lines 1-2 of the Office Action), it is respectfully urged that nowhere does Liu or Petersen, whether taken alone or in any combination, teach the specific combination of ratios of calcium sulfate and the three enumerated salts now required by claim 1.

If the Examiner has personal knowledge of the art that would remedy any of these clear deficiencies in the record, he is respectfully invited to submit a personal declaration under 37 CFR 1.132, making this information of record.

For all of the above reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**D. FEES**

This response is being filed with a petition for a one-month extension of time. The required fee is being submitted via credit card authorization. Thus, no further fee is believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.


**E. CONCLUSION**

In view of the actions taken and arguments presented, it is respectfully submitted that each and every one of the matters raised by the Examiner have been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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